SDA 'The Soap and Detergent Association
475 Park Avenue South, New York, NY 10016

CTFA
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

December 8, 1999

Ms. Debbie Lumpkins
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

RE: Topical Antimicrobial Drug Products - Health Care Antiseptic Drug Products for OTC Human Use Docket number 75N-183H

Dear Ms Lumpkins,

On behalf of the SDA/CTFA Industry Coalition we would like to thank all those from the Agency who participated in the feedback meeting, held November 3, 1999, on the subject of finished product efficacy testing for antiseptic drug products. The Coalition appreciates the time that Agency personnel have taken to review the briefing document and respond to the important questions that have been posed.

On November 5, 1999 the handwritten overhead slides, which captured the essence of our discussion, were forwarded for your attention. We would like to supplement these slides with a brief synopsis of the agreements reached during the meeting, as follows:

Question 1: Does the Agency agree that neutralization of the active ingredient is required in the first and all subsequent sampling steps for all protocols?

The Agency has requested additional data to resolve this issue. FDA and the Industry Coalition will work together to develop a protocol to generate comparative neutralizatidn data for the Healthcare Personnel Handwash, Surgical Scrub and Pre-operative Preparation Methods, using NDA methods (available under the Freedom of Information Act) and methods described in the briefing document.

Question 2: Does the Agency agree that the purpose of the statistical analysis of the efficacy data is to demonstrate the ability of a finished product to meet or exceed an established performance standard and not to demonstrate equivalency to a control product?

There is agreement that finished products must be able to demonstrate an appropriate log reduction, and that parity of performance to a known positive control is not required. The Agency and Industry Coalition concur that a control is necessary to ensure the validity of every test. Industry believes that the control could be any characterized standard. Further discussions are required on the statistical procedures that will be included in the final rule-making; the Agency will provide their proposal in a Feedback Letter.

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Question 3: What is the Agency's view on restricting the efficacy methods detailed in the Final Rule to methods that evaluate finished product?

The Agency agreed that multiple MIC and time kill testing of Category I active ingredients should not be part of the finished product efficacy testing requirements in the final rule-making.

Question 4: What is the Agency's view on the industry proposal to require Time Kill analysis of finished products and to eliminate Minimum Inhibitory Concentration testing for finished products?

It was agreed that the Time Kill test is appropriate for finished product testing. Method details, including the number of indicator organisms, need to be established. The Agency requested a summary paper on existing time kill data, in order to decide if a marker organism approach will be acceptable in the final rule-making.

Question 5: Does the Agency agree that the Cup Scrub Test should be included in the Final Monograph as a method for the evaluation of transient and/or resident organisms on the body?

In principle it is acceptable to include this additional method. The Industry Coalition was requested to forward the latest draft of the ASTM cup scrub test, as well as the other methods that ASTM are developing.

Question 6: Does the Agency* agree *that in the Final Monograph, third party consensus standard setting organizations such as the ASTM are the best means for establishing standardized, accurate and current methods for finished product testing ?

The Agency agrees that there should be a mechanism for updating methods, and is not opposed to the concept of citing ASTM methods, although there are legal and regulatory constraints which will need to be addressed. The Agency and Industry Coalition agreed to explore ways in which ASTM methods could be used as part of the final rule-making.

Question 7: In the Final Monograph, does the Agency intend to reference third party consensus methodology without requiring additional modifications?

In light of the response to Question 6, this question was tabled. The Agency reminded the Industry Coalition that it retains ultimate responsibility for regulatory actions.

Question 8: Does the Agency have any additional concerns with Industry's proposed testing for topical antimicrobial drug products?

A number of issues were raised:

- The Agency and Industry Coalition agreed that a control is needed in all testing to assure the validity of the test (see also Question 2).
- The Agency agrees that the methods should be living documents,
- The Agency and Industry Coalition agreed that products should be designed and tested specifically for the intended use situation.
- A schematic of finished product testing would be helpful. (This is provided as an attachment to this letter.)

Additionally, the Agency indicated that it anticipates issuing a Feedback Letter by the end of the year, summarizing the meeting conclusions and data requests, and addressing the method-specific, detail-orientated issues described in the briefing document. The Industry Coalition looks forward to working with the Agency on the follow-up items arising from the methods meeting and the briefing document in order to resolve the important topic of standardized test methods in the Final Monograph.

Sincerely,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

Jenan Al-Atrash, Dr. PH
Human Health & Safety Director
The Soap and Detergent Association

Attachment I

cc: Robert DeLap, M.D. (HFD-560)
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Linda M. Katz, M.D. (HFD-560)
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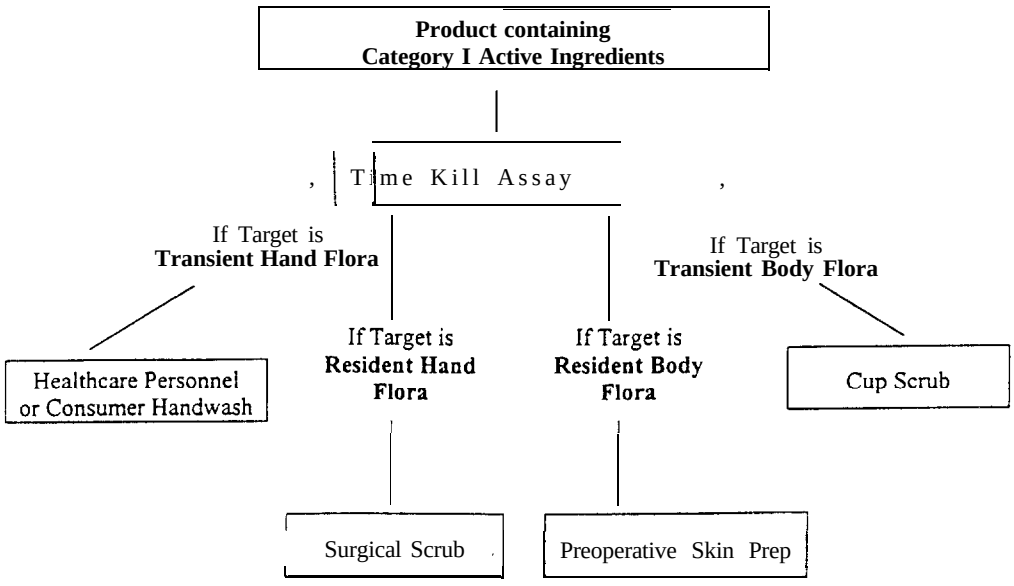

ATTACHMENT I

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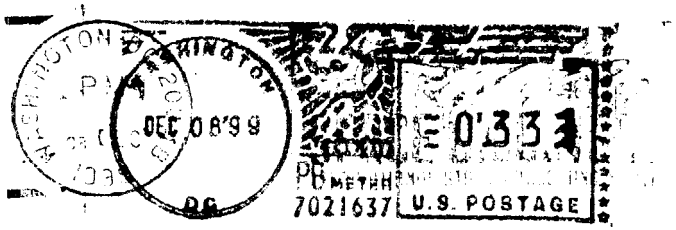

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